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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/293,835 | 04/19/1999 | JAMES C. KENNEDY | 067286/136/D | 5426 |

7590 07/14/2004
FOLEY & LARDNER
3000 K STREET NW
SUITE 500
WASHINGTON, DC 20007

EXAMINER

SHARAREH SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/293,835 | KENNEDY ET AL | |
| | Examiner | Art Unit | |
| | Shahnam Sharareh | 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15, 19, 24, 28-39, 41-47 and 49-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 15, 19, 24, 28-39, 41-47, 49-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment filed on April 07, 2004 has been entered. Claims 1, 15, 19, 24, 28-39, 41-47, 49-52 are pending.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 15, 19, 24, 28-39, 41-47, 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al US Patent 5,283,255 in view of Richter et al US Patent 5,705,518.

Applicant's arguments have been fully considered but they are not persuasive.

Applicant first argues that Levy mentions fungal infections only twice in his patent and goes on to argue that Levy's mention of fungal treatment is not an enabling disclosure (see amendment at p.8).

In response Examiner state that the mere fact that Levy mentioned the use of his methods for treating fungal infections is an indication that Levy envisioned the use of protoporphyrins in treating fungal infections. Levy envisions treating ex vivo infections. Levy recites that photodynamic treatment is effective for treating athlete's foot. Specifically, Levy indicates that his methodology can be employed for treating fungal infections (see col 19, line 4, and lines 19-24). It is established in the art that athlete's foot is caused by tinea pedis and spreads to nail to cause a nail infection known as onychomycosis. Thus, employing photodynamic therapy for treating fungal infections of skin was envisioned by Levy.

Further, all statements in Levy's disclosure is construed to be true and correct statements provided by the Patentee. Accordingly, absence of credible evidence, Examiner would interpret Levy's teachings to be enabling for treatment of athlete's foot and fungal infection.

Applicant then argues that Levy teaches the use of photoactive agents, and not substances which themselves are not photoactive agents, rather precursors of protoporphyrin IX.

In response Examiner states that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, the rejection is based on the combined teachings of Levy and Richter. Richter provides the shortcoming recognized by Applicant. The prodrug of Richter provides the same effect in vivo as other photosensitizing agents such as porphyrins and benzoporphyrins. (col 5, lines 61-col 6, line 5):

Preferred photosensitizing agents include, but are not limited to, chlorins, bacteriochlorins, phthalocyanines, porphyrins, purpurins, merocyanines, pheophorbides, pro-alens and pro-drugs such as δ -aminolevulinic acid, which can produce drugs such as protoporphyrin. More preferred are benzoporphyrin derivatives (BPD) and porfimer sodium.

Accordingly, Richter provides that prodrugs such as 5-aminolevulinic acid is expected to the same way as benzoporphyrins or protoporphyrins would.

Levy teaches methods of treating infections comprising topically administering to a patient benzoporphyrins which are derivatives of protoporphyrin-IX. Levy further administers light to the site of interest where benzoporphyrin is applied. (see abstract, col 7, lines 3-35). Levy does not teach the use of 5-aminolevulinic acid as a photoactive agent for his methodology.

Applicant further alleges that examiner is using an improper "obvious to try" standard which is not the standard for an obviousness rejection (see arguments at p. 10).

In response to such arguments, Examiner states that the Court has addressed this issue in detail in *In re O'Farrell*, 7 USPQ2d 1673 (CAFC 1988). The admonition that "obvious to try" is not the standard under § 103 has been directed mainly at two kinds of error. First when it would have been "obvious to try" to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result and the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. The second, is directed to situations when a new technology or general approach that seemed to be a promising field of experimentation and the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. *Id* at 1681-83.

Neither of these situations applies here. Therapeutic use of proptoporphyrin IX viral, parasite and fungal infections have been know as taught by Levy. Richter specifically recites the use of 5-ALA. Accordingly, all elements of the instant claims were described adequately in the prior art.

Moreover, obviousness does not require absolute predictability of success, only a reasonable expectation of success. There is always at least a possibility of unexpected results, that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious. *In re Merck & Co .*, 800 F.2d at 1098, 231 USPQ at 380; also see *In re Longi*, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985). Accordingly, the rejection of claims is proper for the reasons of record.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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